REMARKS

Reexamination and reconsideration of the pending claims as amended in light of the following remarks is respectfully requested. As applicable, references to the instant patent application text and figures are made by citing to United States Patent Application Publication No. 2004/0224288 A1 (published on November 11, 2004).

I. AMENDMENTS

Claims 1-22 are pending. Claims 1-22 have been amended to improve their form.

Support for the amendments may be found in the application as published. Accordingly, these amendments do not raise an issue of new matter and entry thereof is respectfully requested.

II. REJECTIONS UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

Claims 1-5, 9, 10, and 12-22 stand *"rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention"* (see the Office Action at page 2).

The Examiner has rejected the claims due to the references to "μ" rather than μm. Applicant has amended the claims as suggested to reflect that measurements are in microns/micrometers.

To further prosecution, the symbol "μ" has been amended to include reference to meters (i.e., μm) referring to microns. Applicant notes that the term "micron" and the symbol "μ" are used interchangeably throughout the application as filed. Micron (or

"μ") means micrometer, a.k.a. millionth of a meter, a.k.a 10^{-6} m; and finally a.k.a μm (see also the definition of the word *micron* in Stedman's Medical Dictionary, 26th Edition, Williams & Wilkins, Baltimore, MD, USA).

The Examiner has also rejected the claims on the basis of references to "ISO" standards. Applicant notes that ISO standard measurements are commonly used as short-hand by practitioners, and generally in the field of dentistry to which this invention pertains, to refer to the diameter of instruments to be inserted in the root canal in root canal procedures. These are standard references which are adopted by ISO. These standards are known and clearly understood by those in the field. A specific ISO specifies the taper and tip diameter requirements for root-canal instruments and obturating points. An ISO designation also specifies the dimensions and compositional requirements for prefabricated metal root-canal files and polymeric points or cones suitable for use in the obturation of the dental root-canal. An ISO also specifies numerical systems and a color coding system for designating the sizes of instruments to be used for root-canal procedures. To anyone skilled in the art of endodontics, an ISO value denotes a fixed set of known parameters (see e.g., J.I. Ingle & L. K. Bakland, Endodontics, 4th Edition, Williams & Wilkins (1994) -- Attachment A).

Accordingly, Applicant submits that the amended claims comply with the requirements set forth in 35 U.S.C. § 112, first paragraph as they do particularly point out and distinctly claim the subject matter which applicant regards as the invention. On the basis of the amendments and remarks reconsideration and withdrawal of these rejections are courteously requested.

III. REJECTIONS UNDER 35 U.S.C. § 103(A)

Claims 6 and 8-12 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Levy (U.S. Patent No. 5,622,501) in view of Okamoto *et al.* (U.S. Patent No. 4,979,900).

Applicant avers that the teachings of Levy in view of Okamoto *et al.* do not render the claimed invention obvious for several reasons as discussed below.

Levy is purportedly directed to a tip to facilitate the widening of tooth canals by laser radiation via ablation or vaporization of tissues. (see Col. 1, lines 52-53). For this purpose, Levy proposes a tip which is tapered. In this context, Levy provides that *"if a suitable taper is imparted, laser radiation energy is emitted over the length of the tapered region and is thus spread out along an extended section of the region being treated"* (see Col. 4, line13 *et seq.*). Tapering is *"particularly advantageous for root canal widening (again, via ablation and/or vaporization), or shaping operations [...] without such taper, the radiation is concentrated at the output end of the fiber"* (see Col. 4 lines 17 *et seq.*, underline added for emphasis). In fact, Levy teaches that such concentration would tend to produce a ledge, or notch, in the canal wall. Thus, according to Levy, tapering is crucial for those tips to be inserted in the root canal (*supra*).

Levy's teachings are wholly irrelevant, and actually contrary to the goals of Applicant's invention. In fact, Applicant's invention (because of the characteristics of the surface of the optical probe) does not rely on the tapering *per se* to avoid concentrating radiation on the tip at the output end of the optical probe. To distribute radiation, the instant invention relies on the use of an optically diffusive surface dispersing (sub ablative and sub-vaporative) near infrared optical energy throughout, laterally and along the entire length of the tip according to the amended claims. While

the tip is tapered in certain embodiments, it does not need to be tapered to function as devised by the Applicant as a primary mechanism for "full tooth" biofilm thermolysis.. This is so because Applicant's tip is otherwise configured (e.g., via roughening for scattering and diffusion) to enable optical energy modulation.

Levy claims to utilize the ability of Nd:YAG laser radiation to vaporize dark material to *"selectively destroy bacteria which might be present on tooth or gum surfaces and which will, if undisturbed, cause decay or infection"* (see Col. 6, lines 35 *et seq.*). In fact, Levy provides that bacteria to be eliminated must to be stained to a dark color with a selective stain, and subsequently exposed to a relatively low energy laser radiation which is sufficient to vaporize the bacteria (*idem*). Levy, just like many others in the field, has sought a method to differentially target bacteria while leaving the substrate tissue (e.g., the patient's tissues) unaffected by using staining methods and target laser radiation to stained bacteria. At Col. 6, lines 58 and 59, Levy provides that *"[w]ithout such staining, achievement of similar result would require an energy level of the order of 100 mJ."*

The present invention does <u>not</u> rely on staining to target bacteria. The present invention relies on the photobiology of the near-infrared energy to thermally coagulate the residual biofilm (hence entrapping and killing the bacteria) within all of the dentinal tubules that was not removed chemically and mechanically through traditional root-canal methods. Known methods using Nd:YAG lasers and near infrared solid state diodes are hindered by either (a) the need to stain bacteria with a selective stain to direct radiation absorption to the stained bacteria; or (b) the need to impart a considerable amount of energy (and concomitant damage to the surrounding patient's tissues) in order to achieve thermolysis since bacterial death (following Levy's patent)

is wholly a function of heat depositiont. These problems stem from the fact that the relevant wavelengths are virtually transparent to oral flora. With Levy, the energy cannot be dispersed in the manner of the current invention to gently (without vaporization or ablation) coagulate and thermolyze the remaining biofilm in the dentinal tubules, and trap and kill the bacteria.

To solve this problem, Applicant has thought of a method to augment existing tips to scatter and diffuse optical energy, thereby lowering the required power output from the tip (i.e., at sub-ablative and sub-vaporative energy levels) and increasing the time available for the reduction of biofilm/bacteria.

Levy does not teach or suggest a tip having an optically diffusive surface dispersing optical energy throughout 360° laterally and along the entire length of the tip according to the amended claims. Okamoto *et al.* does not cure this deficiency.

For these reasons, it is submitted that the amended claims are not obvious over Levy in view of Okamoto *et al.* Accordingly, reconsideration and withdrawal of these rejections is kindly requested in light of the foregoing remarks.

Claims 1-5, 7 and 12-22 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Levy (U.S. Patent No. 5,622,501) in view of Okamoto *et al.* (U.S. Patent No. 4,979,900) as applied above and in further view of Kataoka *et al.* (U.S. Patent No. 5,374,266), Nakajima *et al.* (U.S. Patent No. 5,300,067) and Rizoiu *et al.* (U.S. Patent No. 5,741,247).

Applicant avers that the invention of claims 1-5, 7 and 12-22 as amended are non-obvious in light of Levy in further view of Okamoto *et al.* and in further view of Kataoka *et al.*, Nakajima *et al.* and Rizoiu *et al.* for the same reasons set forth above.

Accordingly, withdrawal of the above-recited rejections and reconsideration of the claims as amended are kindly requested.

<< Cont'ed on the next page>>

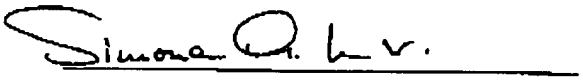
CONCLUSION

In light of the amendments and remarks herein, Applicant submits that the claims are now in condition for allowance and respectfully requests a notice to this effect. The Examiner is invited to contact the undersigned if there are any questions.

A Request for a Three (3) Month Extension of Time, up to and including November 3, 2005 is included herewith. Pursuant to 37 C.F.R. § 1.136(a)(2), the Examiner is authorized to charge any fee under 37 C.F.R. § 1.17 applicable in this instant, as well as in future communications, to Deposit Account 50-1133.

Furthermore, such authorization should be treated in any concurrent or future reply requiring a petition for an extension of time under § 1.136 for its timely submission, as constructively incorporating a petition for extension of time for the appropriate length of time pursuant 37 C.F.R. § 1.136(a)(3) regardless of whether a separate petition is included.

Respectfully submitted,
McDermott Will & Emery LLP



Simona A. Levi-Minzi, Ph.D.
Registration No. 43,750
Attorney for Applicant

McDermott Will & Emery LLP
201 S. Biscayne Boulevard Suite 2200
Miami, FL 33131
Tel.: 305.347.6528 -- Fax: 305.347.6500
email: SLEVI@MWE.COM
Date: November 3, 2005

ATTACHMENT A

obturation. Special techniques, to be discussed later, have been devised to overcome the loss of ***resistance form***.

In Mexico, Kuttler has shown that the narrowest waist of the apical foramen usually lies at the dentinocemental junction (Fig. 3–10).[15] He established this point at approximately 0.5 mm from the outer surface of the root in most cases. The older the patient, however, the greater this distance becomes, because continued cemental formation builds up the apex. One is also reminded that the dentinocemental junction, where ***resistance form*** is established, is the apical termination of the pulp. Beyond this point, one is dealing with the tissues of the periodontal ligament space, not the pulp.

The fact must also be established that the apical ***foramen*** does not always lie at the exact apex of the root. Often, canals exit laterally, short of the radiographic apex. This may be revealed by careful scrutiny of the film with a magnifying glass, or by placing a curved exploratory instrument to the exact ***canal*** length and repeating the X-ray examination. The Japanese reported from a native cohort that the apical foramen exits the exact apex only 16.7% of the time in maxillary anterior teeth.[16]

Extension for Prevention

Seidler once described the ***ideal*** endodontic cavity as a round, evenly tapered space with a minimal opening at the foramen.[14] Because one is working with round, tapered materials, one would think this ideal is easily achieved, particularly when one thinks of root canals as naturally round and tapered. As seen in the anatomic drawings in this chapter, however, few canals are round throughout their length. Thus one must usually compromise from the ideal, attempting to prepare the round tapered cavity, but knowing that filling techniques must be used to make up for the variance from ideal. This is why single point fillings, whether silver or gutta-percha, are seldom used.

The ***extension*** of the cavity preparation throughout its entire length and breadth is necessary, however, to ensure ***prevention*** of future problems. Peripheral enlargement of the canal, to remove all the debris, followed by total obturation is the primary preventive method.

Fig. 3–10. Instruments and filling material should terminate short of cementodentinal junction, narrowest width of canal and its termination at foramen. This point is often 0.5 to 1.0 mm from apex.

Instruments and Methods for Radicular Cleaning and Shaping

Before launching into a detailed or even a broad discussion of the methods and shapes of canal cavity preparation, a description of the instruments and methods used in cleaning and shaping the canal is necessary. "The order of their appearance" during preparation will also be discussed: basic endodontic instruments, irrigation, exploration for canal orifices, exploration of the canal, and length of tooth determination. Then the techniques of intraradicular cavity preparation will follow in detail. Pulpectomy will be discussed later.

Basic Endodontic Instruments

After years of relative inactivity, a remarkable upsurge in endodontic instrument development and refinement has recently developed. Historically, very little was done to improve the quality or standardization of instruments until the 1950s, when two research groups started reporting on the sizing, strength, and materials that went into hand instruments.[45–48] After the introduction of standardized instruments,[49] about the only changes made were the universal use of stainless rather than carbon steel and the addition of smaller (No. 6 and 8) and larger (No. 110 to 150) sizes as well as color coding and the re-emergence of power-driven instruments.

By 1962, a working committee on standardization had been formed including manufacturers and the American Association of Endodontists. This group evolved into the present-day International Standards Organization (ISO). It was not until 1976, however, that the first approved specification for root canal instruments was published (ADA Spec. No. 28), 18 years after Ingle and Levine first proposed standardization in 1958.[17]

Endodontic Instrument Standardization. Before 1958, endodontic instruments were manufactured without benefit of any established criteria. Although each manufacturer used what seemed to be a unified size system, the numbering (1 through 6) was entirely arbitrary. An instrument of one company rarely coincided with a comparable instrument of another company. In addition, there was little uniformity in quality control of manufacture, no uniformity existed in progression from one instrument size to the next, and there was no correlation of instruments and filling materials in terms of size and shape.

Beginning in 1955, a serious attempt was made to correct these abuses, and in 1959 a new line of standardized instruments and filling material was introduced to the profession.[47]

1. A formula for the diameter and taper in each size instrument and filling material was agreed on.

2. A formula for a graduated increment in size from one instrument to the next was developed.
3. A new instrument numbering system based on instrument metric diameter was established.

This new numbering system, using numbers from 10 to 100, was not just arbitrary, but was based on the diameter of the instruments in hundredths of a millimeter at the beginning of the tip of the blades, a point called D_1 (diameter 1) (Fig. 3–11), and extending up the blades to the end points of the blades at D_2 (diameter 2)—16 mm in length.

The full extent of the shaft, up to the handle, is in three lengths: standard, 25 mm; long, 31 mm; and short, 21 mm. The long instruments are often necessary when working in canines over 25 mm long, whereas the shorter instruments are helpful in second and third molars or with the patient who cannot open widely.

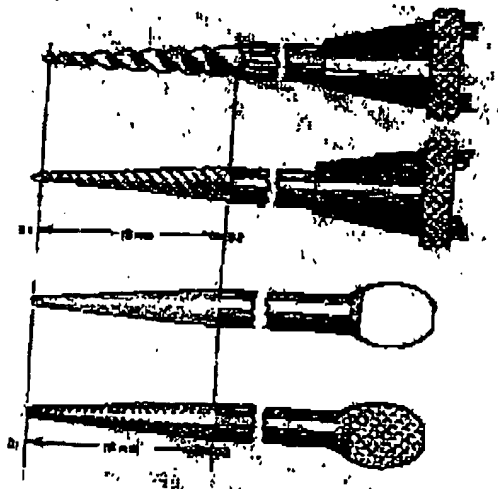
After initial resistance by many manufacturers, who felt that the change would entail a "considerable investment in new dies and machinery to produce them," manufacturers, worldwide, eventually accepted the new sizing.

Ultimately, to maintain these standards, the American Association of Endodontists urged the American Dental Association and the United States Bureau of Standards to appoint a committee for endodontic instrument standardization. A committee was formed [1], after considerable work and several drafts, produced a specification package that slightly modified and embellished Ingle's original standardization. These pioneering efforts reached international proportions when a worldwide collaborative committee was formed: the International Standards Organization (ISO), consisting of the Fédération Dentaire Internationale, the World Health Organization, and the American Dental Association Instrument Committee. The ISO has now formulated international specifications using the ADA proposal as a model.

In January 1976, the American Standards Institute granted approval of "ADA Specification No. 28 for endodontic files and reamers." (Fig. 3–12). It established the requirements for diameter, length, resistance to fracture, stiffness, and resistance to corrosion. It also included specifications for sampling, inspection, and test procedures.[50] The final revision to ADA Specification No. 28 for K-type files and reamers in March 1981 highlighted 25 years of work to achieve international standardization (Table 3–4).[50]

Initially, manufacturers of endodontic instruments worldwide adhered rather closely to these specifications. Some variations have been noted, however, in size maintenance (both diameter and taper), surface debris, cutting flute character, torsional properties, stiffness, cross-sectional shape, cutting tip design and type of metal[51–53] (Fig. 3–13). More recently, Sternman and Spangberg were disappointed to note that the dimensions of root canal instruments are becoming poorly standardized, and that few brands are now within acceptable dimensional standards.[54]

Cormier and Sem have both warned of the importance of using only one brand of instruments because of discrepancies in instrument size among manufacturers.[55,56] Beto also notes that grinding the flutes in files rather than twisting them "does not improve the strength or ductility of the instrument . . . (and) may also create more undesirable fluting defects."[57] Autoclaving apparently has no clinically significant deleterious effects on endodontic instruments.[57,58]



3–11. Original recommendation for standardized instruments. Cutting blades are 16 mm in length and of the same size numbers as standardized filing files. The number of the instrument (diameter at D_1 in hundredths of a millimeter). Diameter 2 (D_2) is uniformly 0.32 mm greater than D_1. (From Ingle, J. I.: Characteristics of the Standardized Instrument. In Endodontics. Edited by L. I. Grossman. Philadelphia, University of Pennsylvania, 1958.)

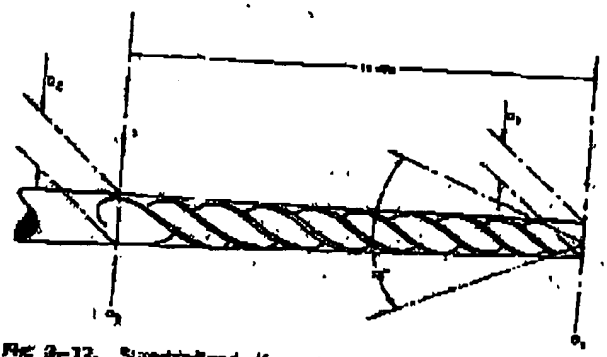


Fig. 3–12. Standardized dimensions of root canal files and reamers established by ISO. Two modifications from Ingle's original proposal are an additional measurement at D_3, 3 mm from D_2, and specification for shapes of tip—75°, plus or minus 15°. The outer of the spiral section must be at 0.02 mm gain for each mm of cutting length. Specifications for a nonCutting tip are forthcoming.

Table 3–1. Dimensions in Millimeters. Revision of ADA Specification No. 28 Added Instrument Sizes 00 and 110 to 150 to the Original Specification

Size	Diameter (Tolerance, ± 0.02 mm) D_1 mm	D_2 mm	D_3 mm	Handle Color Code
00	0.00	0.40	0.14	Gray
10	0.10	0.42	0.16	Purple
15	0.15	0.47	0.21	White
20	0.20	0.52	0.26	Yellow
25	0.25	0.57	0.31	Red
30	0.30	0.62	0.36	Blue
35	0.35	0.67	0.41	Green
40	0.40	0.72	0.46	Black
45	0.45	0.77	0.51	White
50	0.50	0.82	0.56	Yellow
55	0.55	0.87	0.61	Red
60	0.60	0.92	0.66	Blue
70	0.70	1.02	0.76	Green
80	0.80	1.12	0.86	Black
90	0.90	1.22	0.96	White
100	1.00	1.32	1.06	Yellow
110	1.10	1.42	1.16	Red
120	1.20	1.52	1.26	Blue
130	1.30	1.62	1.36	Green
140	1.40	1.72	1.46	Black
150	1.50	1.82	1.56	White

* New diameter measurement point (D_3) was added 3 mm from tip of cutting end of the instrument. Handle color coding is official.

In 1992 Schilder patented a different concept of instrument sizing. Marketed as ProFile Series 29*, the instrument sizes progress by a constant percentage increase (29%) from one instrument to the next, rather than by a metric increase of 0.05 mm between sizes in the standardized ISO instruments.

Although starting with a 0.029 mm increase between files No. 1 and No. 2 ProFiles rapidly gain in metric size to a 0.065 mm increase between sizes No. 4 and No. 5, comparable to ISO sizes 25 and 30.

ProFiles come in sizes "00" to "11," are made of stainless or nickel titanium, and have noncutting tips. No testing has been reported to date.

ISO Grouping of Instruments

In due time, the International Standards Organization—*Fédération Dentaire Internationale* committee grouped root canal instruments according to their method of use:

Group I: Hand use only—*files*, both K-type (Kerr) and H-type (Hedstroem); *reamer* K-type; and broaches, pluggers and spreaders.

Group II: Engine-driven latch type—same design as Group I but made to be attached to a handpiece. Also included are paste fillers.

Group III: Engine-driven latch type—drills or reamers such as Gates-Glidden (G-type), Peeso (P-type) as well as a host of others—A, D, O, KO, T, M-type reamers and the Kurer Root-Facer.

Group IV: Root canal points—gutta-percha, silver, paper.

The ISO grouping of endodontic instruments makes convenient a discussion by group of their manufacture, usage, cutting ability, strengths and weaknesses.

ISO GROUP I—K-Type Instruments, Reamers, or Files. First designed in 1915 by the Kerr Manufacturing Co., these are the most widely copied and extensively manufactured endodontic instruments worldwide. Now made universally of stainless rather than carbon steel, K-type instruments are usually produced by grinding graduated sizes of round "piano" wire into either a square or triangular configuration. A second grinding operation properly tapers these pieces. To give the instruments the spirals that provide the cutting edges, the square or triangular stock is then grasped by a machine that twists it counterclockwise a programmed number of times—tight spirals for files, loose spirals for reamers. The cutting blades that are produced are the sharp edges of either the square or the triangle. In any instrument these edges are known as the "rake" of the blade. The more acute the angle of the rake, the sharper the blade.

There are approximately twice the number of spirals on a file as on a reamer of a corresponding size (Fig. 3–14). Some manufacturers are now grinding in the spirals rather than twisting them. Originally the cross section of the K-file was square, the reamer triangular. Recently, manufacturers have started using either configuration to achieve better cutting and/or flexibility. Cross section is now the prerogative of individual companies.

Reamers. As the name implies, reamers are used for drilling. They cut by being tightly inserted into the canal, twisted clockwise one-quarter to one-half turn to engage their blades into the dentin, and then withdrawn—penetration, rotation, and retraction.[91] The cut is made during retraction. The process is then repeated, penetrating deeper and deeper into the canal. When working length is reached, the next size instrument is used, and so on.

Reaming is the only method that produces a round, tapered preparation, and this only in perfectly straight canals. In such a situation, reamers can be rotated one-half turn before retracting. In a slightly curved canal, a reamer should be rotated only one-quarter turn. More stress may cause breakage. The heavier reamers, size 50 and above, can almost be turned with impunity. The new nickel titanium instruments are much more flexible and resist breakage even in small sizes.

Files as well as reamers can be used for reaming, but conversely, reamers do not work well as files—their flutes are too widespread to rasp.

Files. The tighter spiral of a file (Fig. 3–15) establishes a cutting angle (rake) that achieves its principal cutting action on withdrawal, although it will cut in the push motion as well. The withdrawing cutting action

* ProFile, Tulsa Dental Products (USA)

Executive Editor: Darlene Barela Cooke
Development Editor: Sharon R. Zinner
Manuscript Editor: Jessica Howie Martin
Production Coordinator. Peter J. Carley

Accurate indications, adverse reactions, and dosage schedules for drugs are provided in this book, but it is possible they may change. The reader is urged to review the package information data of the manufacturers of the medications mentioned.

Printed in the United States of America

First Edition, 1965
Reprinted, 1967, 1969, 1970, 1972, 1973, 1974, 1975

Second Edition, 1976
Reprinted, 1978, 1982

Third Edition, 1985

Library of Congress Cataloging-in-Publication Data

Ingle, John Ide, 1919—
Endodontics / John Ide Ingle, Leif K. Bakland; 36 contributors.—
4th ed.
p. cm.
Includes bibliographical references and index.
ISBN 0-683-04810-2
1. Endodontics. I. Bakland, Leif K. II. Title.
[DNLM: 1. Endodontics. WU 230 I51e 1994]
RK351.I5 1994
617.6'342—dc20
DNLM/DLC
for Library of Congress

94-7226
CIP

94 95 96 97 98
1 2 3 4 5 6 7 8 9 10